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The Risks and Benefits of Participating in Trauma-Focused Research Studies

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Concern about minimizing harm and maximizing benefit has been particularly acute with regard to the scientific study of individuals exposed to potentially traumatic events such as terrorist attack or disaster. This review outlines conceptual and practical issues and summarizes available evidence regarding potential risks and benefits of participation in trauma-related research. Current, limited evidence suggests that most individuals make favorable cost–benefit appraisals regarding their participation. Although a subset of participants report strong negative emotions or unanticipated distress, the majority of these do not regret or negatively evaluate the overall experience. Continuing efforts are needed to identify individuals at risk for unfavorable reactions to research participation. A systematic empirical approach to evaluating participant experience in all human research is recommended.

KEY WORDS: experimental ethics; experimental subjects; posttraumatic stress disorder; risk analysis; risk–benefits analysis; study protocols; disaster.

Both ethics codes and government regulations require researchers to identify all pertinent risks so that potential subjects are able to make informed judgments about research participation on the basis of knowledge of potential consequences, including harm that might result. Specifying risks associated with general research participation can be challenging because participants present with a range of potential vulnerabilities. The situation is further complicated for disaster-related research because potential participants may be struggling with psychological, medical, economic, and social difficulties secondary to the disaster. The impact of these factors on particular individuals can be difficult to know in advance and may influence judgments about research participation in divergent ways. For example, the effects of disaster may make it particularly burdensome for individuals to devote time to research participation or, on the other hand, such effects may make it more attractive for individuals to receive payment or to have an opportunity to share personal details of a harrowing experience.

All researchers must accommodate individual differences in risk–benefit perspectives when constructing study procedures and writing consent forms, but they often lack a reliable point of reference for decisions about how to do so. As a result, researchers resort to commonsense approaches that leave them vulnerable to widespread decision-making errors such as overreliance on single-case examples, underutilization of base rate information, and risk estimates based on the salience of outcomes rather than actual risk probability (see Thomson, 1996, for an extended discussion of this issue). In the case of disaster-related research, for example, it is often assumed that affected individuals require special protections because it can be distressing to disclose trauma-related information. This view fails to take into account evidence that such disclosure is regularly followed by emotional relief that many participants identify as a benefit of the experience.

Clearly, investigators need to be alert for negative impact that their study procedures may have on participants, and they need to devise protocols to minimize

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all potential risks. On the other hand, investigators must not be deterred from conducting meaningful and beneficial studies because of uninformed decisions or prejudice. One option is to use scientific evidence to guide subject protection decisions in research practice. Fortunately, over the past 5 years, researchers have begun to adopt an empirical approach to addressing some of the ethical dilemmas encountered during trauma-related investigations.

This paper outlines some key issues and reviews existing evidence regarding participation in trauma-related research from the perspective of human subjects protection. We begin by identifying issues related to costs and benefits of participation and then present a systematic approach to evaluating the decision-making process. Next, we review the empirical literature about research participants' appraisal of risks and benefits of trauma-related research. Finally, we summarize the available evidence and raise issues for further discussion.

Cost–Benefit Analysis

Most trauma-focused studies ask participants to report on traumatic life experiences and the resultant effects on themselves and their lives. Typically this includes assessment of mental health symptoms and some aspects of role functioning (e.g., work performance; social relationships). Some research protocols involve challenge tasks during which subjects are exposed to visual or auditory reminders of their traumatic experiences so that acute reactions can be measured. Some administer laboratory tests aimed at theoretical mechanisms underlying response to traumatic stress. Many protocols involve administration of experimental treatments accompanied by measurement of target outcomes. Others involve the use of focus groups. Although each trauma-related research protocol has its particular set of potential risks and benefits, Table 1 lists some of the typical risk and benefit consideration that might be relevant across studies. The

Table 1. Potential Risks and Benefits of Research

Risks	Benefits
Participants	
• Physical harm	• Material Resources
Infection	Money
Pain	Food
Health problems	• Medical/mental Health Services
Disability	• Empowerment
• Legal action	• Learning/insight
Mandated reporting of abuse	Reducing stigma/normalizing trauma-related reactions
Deportation/immigration	Breaking silences/disclosure of information in an accepting setting
Criminal/civil Proceedings	• Altruism
Research records subpoenaed	• Kinship with others
• Inconvenience	• Feeling worthwhile by participating
Boredom	• Receiving favorable attention by researcher
Frustration	
Wasting of participants' time	
• Economic risks	
Loss of wages, employment	
• Psychological/mental	
Discomfort	
Worsen condition	
Cause painful memories	
Evoke strong emotional distress	
Evoke shame, anger, fear, other painful emotions	
Foster self-destructive behavior	
• Social risks	
Breach of privacy	
Rejection by others	
Adversely affect others in social network	
Societal	
• Give science a bad name	• Scientific knowledge/outcomes
• Create burdens for care delivery service that cannot be met	• Greater training to care delivers/augment services
Researchers, host institutions	
• Bad press	• Foster valuable relationships
• Vicarious traumatization of research staff	• Gain resources
• Breach of confidentiality	• Gain recognition
• Legal action	
• Potential political impact of findings	

listing reflects multiple perspectives including that of participants, researchers, hosting institutions, and the broad interests of society and it highlights the challenge of the task at hand.

To meet the challenge, we have proposed a systematic, multistep process to guide information gathering relevant to decisions about human subjects protection in trauma research (Newman, Kaloupek, Keane, & Folstein, 1997). The first step in applying this approach to a specific research protocol is to identify areas of uncertainty about ethical issues or subject safety. Each issue is then posed as a hypothesis that can be tested empirically. Data gathering begins with a search for relevant existing evidence. Data sources include both published literature and colleagues with experience in the field. This initial process may eliminate some concerns, validate others, and raise additional ones for consideration. Carefully enumerating the issues and clarifying potential risks and benefits makes it easier to generate options aimed at reducing risk and increasing benefit. Once a viable protocol is created, attention turns to the task of collecting data regarding research participants' experience with it. Data of this type provide a means both for identifying individuals who may warrant special attention (e.g., due to distress about or dissatisfaction with the experience) and for generating a potentially publishable body of work that can inform the field about the subjective impact of participation in trauma-focused studies.

Evidence Regarding Benefits and Risks to Research Participants

There is an emerging empirical literature on participants' appraisal of the trauma-related research experience summarized in Table 2. The 12 studies were identified by computerized bibliographic search of PsychINFO and PILOTS using the terms "experimental ethics" and "trauma," reviewing the reference list of each article to identify additional citations that were not revealed by those searchers, and e-mailing or contacting individuals who had asked for permission to use the Reactions to Research Participation Questionnaire (RRPQ) or had presented relevant data at the ISTSS convention and requesting copies of in-press or unpublished articles. Although only 1 of these 12 studies focuses on disaster survivors (Galea, Stuber, & Gold, 2003), 2 include individuals who were seeking treatment due to physical injuries from recent stressful life events (Kassam-Adams & Newman, 2003; Ruzek & Zatzick, 2000) and one included assessment of acute assault survivors an average of 10 days postassault (Griffin, Resick, Waldrop, & Mechanic, 2003). The remaining investigations examine trauma-exposed refugees (Dyregrov, Dyregrov, & Raundalen, 2000), college students (Newman, Willard, Sinclair, & Kaloupek, 2001), military veterans (Parslow, Jorm, O'Toole, Marshall, & Grayson, 2000), survivors of child abuse (Carlson et al., 2003; Dutton et al., 2002; Martin et al., 1999; Newman et al., 1999; Walker et al., 1997), and partner violence (Dutton et al., 2002). The studies vary with respect to sample, aims, research design, and the particular risks and benefits they involve, but some cross-study comparisons are possible because 6 of the 12 studies used questions derived from a version of RRPQ, a measure designed to assess participants' judgments about key ethical constructs including risks, benefits, and cost–benefit appraisal (Kassam-Adams & Newman, 2002; Newman, Willard, et al., 2001). These few studies form a foundation for examining the risks and benefits of trauma-related research.

Benefits

Rewards and benefits of participating in research on disaster, violence, and trauma need to be studied and documented so that researchers have guidance about how to maximize such outcomes. For example, information regarding availability and helpfulness of mental health referral made routinely available to study participants may provide useful proxy measures of benefits. Anecdotal examples of benefits include self-identified insights or improvement in well-being that result from reflecting on traumatic life events in a safe context, or even simple diversion from life challenges and emotional pain. On a broader scale, many people receive satisfaction from making a contribution to the welfare of others by serving as research volunteers. Because actual benefits of research participation, as opposed to intended benefits, vary across individuals and often cannot be guaranteed, trauma researchers have studied realized benefits retrospectively using both structured and unstructured methods.

In those studies using items from RRPQ, participants endorsed a variety of positive gains from research involvement (Dutton et al., 2002; Kassam-Adams & Newman, 2003; Newman et al., 1999; Newman, Williard, et al., 2001; Ruzek & Zatzick, 2000; Walker et al., 1997). For example, 77% of acutely injured children and 74% of their parents reported benefit from participation in a study by Kassam-Adams and Newman (2003). Half of both children and parents reported positive self-esteem because of participating, and 50% of the children and 90% of parents felt good about their altruism. Similarly in a study of 117 acutely injured adults (Ruzek & Zatzick, 2000), 95% endorsed an item indicating that benefits outweighed the

Table 2. Summary of Research

Study	Sample	. Study/intervention	Assessment of participants	Distress/upset	Informed consent	Benefit/ usefulness	Cost–benefit
Galea, Stuber, & Gold (manuscript submitted for publication)	Random digit dial telephone surveys of 5776 NYC dwellers	Telephone survey regarding 9/11 exposure and mental health response	Question if survey was upsetting, if still distressed at end of interview, wants assistance from a counselor, whether needs is immediate or next day	12.9% who completed surveys found upsetting, but 1% still felt upset at conclusion, and 0.3% (wanted assistance from counselor)	Not assessed	Not assessed	Not assessed
	1008 6–8 weeks post-9/11 2011 4–5 months post-9/11 2755 6–9 months post-9/11			Slightly higher percent (15%) upset during the first wave of interview 6–8 weeks post event Those with more symptoms found the survey questions upsetting			
Dutton, Czaja, & Widom (2002)	Study 1: 406 urban battered women from courts and shelters	Study 1: Interviews, 3 month phone interviews, first year	Study 1: Modified RRPQ[a] at 1 year	Study 1: Intense emotions = 2.71,[b] unexpected distress, = 3.7, intrusions = 3; Increased emotional response predicted by PTSD (Mean personal drawbacks score = 4.4 and personal questions item =3.6)	Not available	Study 1: 4.7[b] = personally meaningful	Not available
	Study 2: 502, mostly low SES men and women	Study 2: field interviews, 3 finger prick blood samples	Study 2: Several RRPQ items	Study 2: Intense emotions = 3, unexpected distress, = 3.1, intrusions = 3; Minority status, feeling different, current depression and lifetime PTSD predicted increased emotional reaction; (Questions too personal = 3.9)		Study 2: 3.9[b] = personal meaningful.	
Kassam-Adams & Newman (2003)	203 children and 200 parents who received hospital services for traffic-related injuries	Interview with parents and children within 1-month postinjury	RRPQ-C and RRPQ-P	5% of children & 5% of parents upset/sad; Those with ASD more likely to report feeling sad or upset (and boredom too); Greater proportion of those younger reported sadness/upset Boredom was endorsed by 19% of children and 8.5% of parents	Younger children reported less choice	77.3% of children; 90% of parents felt "good about helping other people by being in this study"	3 of the 10 upset kids reported regret, 4 reported being glad; 4 of 10 parents reported regret, 6 reported glad

Table 2. Continued

Carlson et al. (2003)	223 psychiatric inpatients	Interview and self-report items about trauma history and symptoms-Trauma history, aggression, PTSD, dissociation	2 items—upsetting, perceived usefulness,	6.6% discontinued, 24% very or extremely upset (risk: past trauma, current symptoms)	Not Applicable	51% useful (somewhat or more)—no clear predictors	Of 49 high upset, 37% found at least somewhat useful On content analysis, upsetting part also may be most useful (upset remembering past and led to new insights as benefit)
Griffin et al. (2003)	Study 1: 170 female survivors of interpersonal violence 2 weeks postassault	Study 1: Psychological and psychophysio-logical assessment	Likert ratings of distress, interest in tasks, assessment length, emotional numbing, and willingness to be assessed again in future	Study 1: 41% felt strong feelings during assessment 2% highly distressed on paper-and-pencil questionnaires, 4% on computer-based questionnaires, 8% on clinical interviews, 48% on trauma phase, and 10% overall and on neutral phase of psychophysiological assessment, 3% on videotaped assessment	Not assessed	Not assessed	Study 1: 5% reported unwillingness to be similarly assessed again
	Study 2: 260 domestic violence survivors	Study 2: All completed psychological assessment and 130 subset had psychophysiol-ogy assessment and extended clinical interviews,		No differences related to PTSD status, trauma exposure type except those with PTSD-rated greater distress and difficulty talking about trauma during psychophysiological assessment Study 2: 42% felt strong feelings during assessment; 3% highly distressed on paper-and-pencil questionnaires, 5% on computer-based questionnaires, 10% on clinical interviews,			Study 2: 2% reported unwillingness to be similarly assessed again
Newman et al. (200l)	613 college students	PTSD, trauma history	RRPQ	Those with probable PTSD rated less upsetting than those without PTSD	Not reported	Those with PTSD found more benefit	Not reported

Table 2. Continued

Study	Sample	. Study/intervention	Assessment of participants	Distress/upset	Informed consent	Benefit/ usefulness	Cost–benefit
Ruzek & Zatzick (2000)	117 physically injured hospitalized MVA and assault survivors, ages 14–61	1-h interview from 1 to 9 days after admission; $10 reimbursement included PTSD measures, depression, dissociation, traumatic life events, substance use	10 items of RRPQ (2 adverse response, 2 cost–benefit, 3 control over stopping. starting, 1 consent comprehension, 2, benefit)	11% unexpected distress 32% reported protocol made them think of things they didn't want to think about Age, not ASD predicted unexpected distress, intrusions, difficulty declining initial involvement. Injury predicted unexpected set	98% understood consent, 94% felt free to skip question, 97% know could stop at any time,	95% benefit; 82% reported feeling good about self for participating	95% found benefits outweighed costs; 98% had not regrets
Parslow et al. (2000)	Follow-up of an epidemiological study of 641 male Australian army Vietnam veterans	Interview about Vietnam, PTSD module	One Likert questions about distress thinking about event during interview, one question "people like these researchers should leave (them alone) on questionnaire"	30% reported distress 11% subthreshold distress;	Not assessed	Not assessed	Distress was not associated with withdrawal from study or additional use of medical services
		2 weeks later questionnaire on Vietnam		Group with current PTSD-endorsed statistically significantly highest percentage of distress			
Dyregrov et al. (2000)	9 families consisting of 29 Bosnia refugees (6–73 years)	Follow-up of reactions to previous family interviews lasting 3.5–6 h, 17 with interpreter–adults asked about flight from homeland	Questionnaire and semistructured interview about research experience by same interviewers	All said it was hard—unspecified "depression, sad, etc.," younger children reported more negative overall appraisal although unclear if statistically significant	Not assessed	All said that research made them rethink and analyze situation; all men and 2 women wanted to talk more about the worst things	For evaluation, 4.5 women; 4.5 men (scale 1–5)
			One Likert scale (1 negative – 5 positive) general evaluation of research experience				1 of 5 adolescents rated experience as is negative, 3 as neutral

Table 2. Continued

Newman, Walker, & Gefland (1999)	1,174 females enrolled in an HMO who completed questionnaires, 252 females who completed follow-up interviews, and 218 females who completed 48 hour follow-up assessment	Study of trauma, health, and health utilization in HMO sample	Three questions (1) Positive gain	10.5% on questionnaire, 19.1% on interview, 22.5% 48+ h	Not assessed (although unexpected upset relates to this)	Questionnaire—25% yes, 16% no, interview 86% benefit, 0 no, 48-h follow-up 85% benefit, 1 person no	5% on questionnaire, 1 person regret at questionnaire, 0 regret at follow-up
			(2) Upset more than expected (3) No regret				*Lower symptoms related to regret *Regret not related to maltreatment status *Of those with unexpected upset, 14 (1.1%) regretted participation
Martin, Perrott, Morris, & Romans (1999)	2 phase study of 497 randomly selected women who responded to questionnaire about abuse; then interviewed all who screened positive for abuse and equal nonabused; 6 years later 354 women were reinterviewed	Mental health, parental child relations, trauma history,	Second interview – 6 years later (memories of last interview were mean of 2.35 clarity (1–5 Likert)	How she felt about last interview (positive, neutral or negative); comfort discussing (Likert 1–5)	Nonabused group more comfort than abuse group;		Half said positive, 31% neutral, 6% negative (others nonrated)
		Second interview–health, coping, dissociation					More abused women rated favorably
Walker, Newman, Koss, & Bernstein 1997	330 females enrolled in an HMO	Questionnaires regarding trauma, health, and health utilization in HMO sample	Three questions (1) positive gain	13% had unexpected upset (of which only 1.2% had regret)	Not assessed (although unexpected upset relates to this)	25% positive gain, 13% no positive gain	Regret related to child maltreatment status
			(2) upset more than expected (3) No regret	Trauma history, PTSD and abuse history predicted unexpected upset			

[a] RRPQ = Reactions to Research Participation Questionnaire.
[b] Higher scores, because of reversal of items, denote more favorable reactions/positive rating in a Likert Scale from 1 to 5, unless otherwise noted.

costs of participation and 98% endorsed an item indicating no regrets about participation. Among the first 330 respondents who completed a trauma-related health survey, 25% reported positive gain from a trauma-related health questionnaire (Walker et al., 1997). In the full sample of randomly selected HMO enrollees, benefit was endorsed by 24% of the 1,174 questionnaire respondents, 86% of the 252 interviewed in Phase 2 of the study, and 85% of the 218 contacted 48 h after the interview (Newman et al., 1999).

Content analyses of open-ended responses in two studies reveal that participants found it useful to reflect on and think about their experiences, even painful ones. In a study of 29 child and adult refugees, all reported relief lasting several days after the interview. In addition, 4 out of 14 children commented that it was useful to talk to someone outside the family, and 6 children reported that it helped them clarify personal issues related to refugee status (Dyregrov et al., 2000). Content analysis conducted by Carlson et al. (2003) on 140 open-ended responses about research participation by psychiatric inpatients showed 35.6% reporting that participation led to new insights, 16.4% finding it generally helpful to be able to talk about their experiences, and 12% reporting that it clarified past memories.

It is unclear which characteristics mark individuals who benefit most from trauma-related studies. Among college students, those with probable PTSD have been found to endorse higher scores on the Perceived Benefits scale of RRPQ, which included items related to insight, benefit, and meaningfulness (Newman, McCoy, & Rhodes, 2001). A history of child maltreatment was found to have no relationship to perceived benefit in one study sample (Newman et al., 1999; Walker et al., 1997), but was related to overall positive appraisal of the research experience 6 years after participation in another (Martin et al., 1999). Clearly, more research is needed to further understanding about participants' appraisals of benefits in trauma-related protocols so these can be maximized, including long-term studies that track beneficial health outcomes including positive help-seeking behaviors such as entry into mental health treatment.

Emotional Distress

Quantifying the prevalence and correlates of emotional distress experienced during trauma-related research provides vital evidence that can guide investigators' efforts to identify vulnerable participants and devise protocols that minimize risk. Unfortunately, the issue of emotional distress is often mischaracterized in terms of the potential for a protocol to "retraumatize" research subjects. Use of this term is unwarranted in the research context because it equates recounting a traumatic experience with the actual occurrence of traumatic exposure. It essentially ignores the distinction between distress that emanates from recall of an experience and, for example, the "intense fear, helplessness, or horror," (American Psychiatric Association, 1994, p. 424) that emanates from direct experience with a traumatic stressor. A key consideration is the uncontrollability that is inherent in most traumatic situations, which contrasts with routine efforts that are made to enable participants to exert control in a research context, including the ability to terminate participation at any time. Failure to recognize this distinction undermines efforts to balance the risks and benefits of research participation by exaggerating the risk aspect.

It is likely that a nearly universal concern of IRBs is the potential for emotional harm due to recall of traumatic events. Investigators share this concern, so it is not surprising that the majority of studies in our review included some attempt to measure emotional distress caused by research procedures. Researchers have examined both the magnitude of distress and the relative experience of distress compared to a participant's prior expectations. In all studies, a small subset of research participants indicated some degree of marked or unexpected upset. For example, 5% of children and 5% of parents who participated in the Kassam-Adams and Newman (2003) study of acute injury reported feeling sad or upset during the research. An unpublished reanalysis of college students' individual item responses to RRPQ (Newman, Williard, et al., 2001) revealed that 9% experienced intense emotion, 3% rated feeling out of control, and 1.8% rated their condition as worsening. Unfortunately, neither of these studies examined whether the acute distress persisted. The one study that examined unexpected upset 48 h after the initial interview found that 7% of the sample experienced an increase in upset over this period whereas 3% experienced a decrease. This pattern suggests that distress (or lack thereof) is fairly stable after participation, but there is some indication that distress levels can change for a small subset of participants (Newman et al., 1999).

Galea et al. (2003) examined research-related distress, in part, by noting how many individuals requested information on mental health services that were made available on a routine basis to all participants in their study. Among those New York City dwellers participating in three population surveys of responses to the September 11 terrorist attacks, only 19 (0.3%) of 5,774 respondents who completed the surveys wanted assistance from a counselor. It is likely that at least some of these individuals

were seeking professional services for distress not due to participation per se because professional assistance also was sought by 10 individuals who were contacted but who did not complete the surveys. Even if all 29 did seek help for research-related distress, this is an extremely small minority of the participants and not suggestive of a special human subjects protection issue.

Among the various samples, psychiatric inpatients and Vietnam veterans had the greatest proportion of participants indicating distress (Carlson et al., 2003, Paslow et al., 2000). In the study of psychiatric inpatients, 6.5% of those who began the interviews discontinued because of upset, and another 24% who completed interviews rated themselves as very or extremely upset by the questions. Of 126 participants in this study who answered the question about what aspect of the interviews was upsetting, 46.4% identified remembering the past and/or recognizing memory gaps, 16% reported the detailed nature of the questions, 11.2% reported experiencing painful insights, 7.2% reported that the protocol evoked negative emotions, and 7.2% said it was upsetting to talk about the trauma.

Several participant characteristics have been identified as potential risk factors for emotional reactions to trauma-related research participation, although these vary substantially across samples. Some studies found that current or past trauma-related distress increased the likelihood that participants would report marked or unexpected upset following participation (Carlson et al., 2003; Dutton et al., 2002; Galea et al., 2003; Kassam-Adams & Newman, in press; Newman et al., 1999; Walker et al., 1997). Current symptomatic distress unrelated to trauma also showed this pattern (Dutton et al., 2002; Walker et al., 1997). In contrast, college students with probable PTSD rated the experience of research participation as significantly *less* emotionally upsetting than those without PTSD (Newman et al., 2001). Among injured adults, no relationship was found between trauma-related distress and postparticipation upset (Ruzek & Zatzick, 2000). Finally, as expected, those with PTSD had greater difficulty and distress during the phase of assessment when the participant had to describe the traumatic event, than those without PTSD but there were no differences during beginning or final phases of the assessment related to PTSD status (Griffin et al., 2003).

Additionally, two research teams found that subjects with histories of trauma were more likely to underestimate or experience upset (Carlson et al., 2003; Newman et al., 1999; Walker et al., 1997). In a study of childhood sexual abuse, the characteristics of social vulnerability (i.e., minority status; feeling different), current depression, and lifetime PTSD symptoms all were associated with greater emotional response experienced during the research protocol (Dutton et al., 2002). In those samples that included a wide range of ages, reports of distress were also more common among younger children and older adults (Dyregrov et al., 2000; Kassam-Adams & Newman, in press; Ruzek & Zatzick, 2000). Finally, greater injury severity increased the likelihood of endorsing unexpected upset (Ruzek & Zatzick, 2000). Given the limited number of studies, it is unclear how much these predictors vary in relation to sample characteristics, measurement methods, or other procedural features.

Available evidence demonstrates that negative emotions are experienced by at least some individuals during participation in trauma-related studies. However, it does not address how such upset compares to the magnitude of distress these individuals confront during their daily lives, and whether the upset reflects acute intensification of their typical symptoms or involves emotional responses that are uncharacteristic for them. Addressing these questions is important because the answers can help to establish whether emotional distress experienced during particular trauma-related research qualifies as "minimal risk." *Minimal risk* is defined as the probability that magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those *ordinarily encountered in daily life or during the performance of routine physical or psychological examinations and tests* (National Commission for the Protection of Human Subjects of Behavioral Research, 1978). It is in the interests of individual investigators to collect their own postparticipation data addressing this issue, given our limited ability to draw on existing evidence to address it. Investigator-driven evidence has the potential advantage of being relevant to future research conducted by the investigator (e.g., in terms of methods and samples); therefore, it can be used to inform planning and support submissions to IRBs.

It should be noted that emotional distress is not unique to trauma-related studies. For example, of 873 elderly participants who completed a community mental health survey, 4% reported experiencing distress during the research protocol and 1% reported that participation depressed them (Henderson & Jorm, 1990; Jorm et al., 1994). According to a survey of a mixed group of 90 funded scientists who studied either mental health, cognition, or lung–cardiovascular disease, 57% reported that some participants cried, with 9% reporting that this occurred regularly (Newman, McCoy, et al., 2001). Given that the issue of distress and emotional reactivity during research is applicable to studies outside the field of traumatic stress, there is value in gathering evidence from a variety of samples, research designs, and research topic

areas to provide greater generalizability and a broader foundation for estimating base rates for these risks.

The Relationship Between Regret About Participation and Upset

While reactive distress is an important consideration in trauma-focused research, it needs to be understood in relation to other experiential aspects of research participation that help to define its functional impact on the participant. This point is demonstrated in general terms by the psychometric analysis of RRPQ among college students (Newman, Williard, et al., 2001) that showed that scores on the emotional reaction factor correlated only weakly with scores on both the perceived personal benefits and drawbacks factor, and only moderately with scores on the general satisfaction with participation factor, and the overall RRPQ score. Across studies that have examined individuals who were markedly or unexpectedly upset, findings show only a small proportion who regretted participation or rated the overall experience as negative (Kassam-Adams & Newman, in press; Newman et al., 1999; Ruzek & Zatzick, 2001; Walker et al., 1997). For example, at the end of a trauma-focused interview, 48 (19%) of the participants felt the experience was more upsetting than anticipated, but only one person registered regret about having participated (Newman et al., 1999). Among 10 acutely injured children who reported sadness or upset during research procedures, 3 regretted participation, whereas 4 reported "being glad" that they had participated. In a study of veterans, Parslow et al. (2000) found that distress was not associated with withdrawal from the study or changes in health care utilization. Similarly, Carlson et al. (2003) found that, of the 49 psychiatric inpatients who reported high upset, 39% still found participation useful. Content analysis of the responses given by these participants showed that "remembering the past" was the most prominent reason given for why the interview was upsetting, but it was also the means identified for achieving insight, the most cited benefit. These findings indicate that we need to look beyond distress in our search for understanding about participants' judgments about costs and benefits of the research experience.

Other Risks

There is little evidence regarding other risks associated with trauma-focused research. Examination of individual item responses to RRPQ shows that 5.2% of the college student subjects reported that the study procedures made them feel stupid, 10.2% reported inconvenience, and 10% found participation boring (unpublished analysis of data reported in Newman, Williard, et al., 2001). College women endorsed more perceived drawbacks from study participation than did men (e.g., inconvenience, boredom, personal questions, and time burden). Likewise, Kassam-Adams and Newman (in press) found that 19.2% of acutely injured children and 8.5% of their parents reported boredom in relation to study participation.

Urquiza, Wyatt, and Goodlin-Jones (1997) have used case studies to illustrate a risk not to participants, but to research team members. They described how certain members experienced upset when conducting trauma-focused research tasks. Similar distress was noted in lay interviewers administering a non-trauma-focused mental health survey (Turnbull, McLeod, Callahan, & Kessler, 1988). These studies suggest the need for screening and training research staff, as well as further efforts to document this risk.

Disaster research may involve a unique risk that warrants attention. Especially in high-profile disasters, affected individuals may be recruited by multiple research teams, leading to excessive time burden for subjects, as well as concerns stemming from the fact that none of the individual investigators or their IRBs may have a full picture of what potential participants are experiencing under the collective onslaught (Fleischman & Wood, 2002). Agencies responsible for coordinating relief efforts are unlikely to invest time doing the same for research. Apart from the direct impact on individuals, both potential participants and the public at large may perceive the resulting free-for-all in subject recruitment as insensitive and exploitative, giving the research enterprise a negative image.

Summary and Issues for the Future

In the past 5 years, a number of studies have examined trauma-related research risk and benefits. Although each has methodological limitations, collectively they represent an important step forward in the effort to develop measures of participants reactions to trauma-related research. Overall, it appears that the majority of participants in these trauma-related studies report favorable perceptions of the cost–benefit balance. However, some participants do experience strong negative emotions or more distress than anticipated during the research protocol. Despite some inconsistencies across studies and samples, initial evidence suggests that preexisting distress, younger and older age, a history of multiple trauma exposure, social

vulnerability, and greater physical injury severity may increase the likelihood of marked or unexpected distress in trauma-related protocols.

It is noteworthy that the majority of subjects who experience strong emotional reactions do not regret or negatively appraise their research participation. This confirms the suggestion that emotional distress can be understood as an indicator of emotional engagement with a research project rather than as a de facto indicator of harm (Dyregrov et al., 2000). Still, an appreciable subset of participants do express regret about participation, a proportion of whom also reports marked or unexpected distress. At this point, it is unknown whether such distress exceeds the range of minimal risk because we do not know whether or not these are new symptoms and whether or not the symptoms preexist but are intensified or sustained as a result of research participation. It is important to continue efforts to identify these individuals a priori so that precautions can be taken to maximize benefit and minimize harm. And, of course, the informed consent process must clearly acknowledge that research participation may result in distressing emotions during or after the protocol so that informed decisions can be made by potential participants.

The study of risks and benefits needs to continue across all types of research because the issues are not unique to trauma-related investigations. Still, trauma researchers need to be especially proactive in gathering empirical evidence to delineate both the relative vulnerabilities of their research participants and the relative costs and benefits to participants of research protocols. Information gathered in the course of a study can be used dynamically to direct the protocol in ways that increase benefit or reduce harm as the study is conducted. This can be accomplished by monitoring indicators of distress, perceived harm, benefit, and so forth, on a subject-by-subject basis so that suitable individual action can be taken. In addition, the composite data across subjects provides evidence to the investigator regarding their efforts to make the protocol safe and risk-free.

On a broader lever, measurement procedures that address ethical concerns might be routinely incorporated into research protocols, and findings drawn from these measures can be included in formal research reports. For example, researchers might routinely summarize information about participants' ratings of risks and benefits in the protocol. Eventually such practices could evolve into a formal section on ethics in the research report to address the nature of risk–benefit analysis, informed consent, confidentiality, and the types of problems encountered during the conduct of the study, solutions generated and their effectiveness (Miller & Rosenstein, 2002).

As we gather information about research risks and plan actions to reduce them, we need to carefully evaluate how we will apply the principle of autonomy to our decision making. *Autonomy* refers to respecting the wishes of those who are competent to make choices and protecting those with impaired abilities. In addition to respecting an individual's ability to make decisions, the principle of autonomy is generally interpreted as a commitment to treating individuals with respect and dignity in all matters. For example, there is no evidence that experience with trauma impairs the ability to make an informed choice about participating in a study even if participation carries risk of emotional discomfort. Therefore, it can be argued that preemptory use of someone's exposure to trauma as the basis for withholding the opportunity for research participation would violate this principle.

The goal of this paper was to review evidence and raise issues about trauma-related research to inform discussion regarding the ethical conduct of research with individuals exposed to disaster. Our brief review presents initial empirical approaches to these issues and evidence regarding methods for assessing the impact of our research practices on the individuals who serve as volunteer participants in these efforts. As we consider the ethical dilemmas encountered in conducting meaningful and safe disaster research, we urge researchers to use scientific methods of assessment and communication to bring greater clarity and accuracy to the field.

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